EXHIBIT A

2024 WL 4625719
Only the Westlaw citation is currently available.
United States District Court, D. Hawai'i.

STATE OF HAWAI'I, EX REL. ANNE E. LOPEZ, ATTORNEY GENERAL; Plaintiff,

v.

CAREMARKPCS HEALTH, L.L.C., EXPRESS SCRIPTS, INC., OPTUMRX, INC., Defendants.

CIV. NO. 23-00464 LEK-RT
|
Filed 10/30/2024

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

Leslie E. Kobayashi Senior U.S. District Judge

***1** On January 5, 2024, Defendants CaremarkPCS Health, L.L.C. ("Caremark"), Express Scripts, Inc. ("Express Scripts"), and OptumRx, Inc. ("OptumRx" and collectively "Defendants") filed their Motion to Dismiss Plaintiff's First Amended Complaint ("Motion"). [Dkt. no. 57.] Plaintiff State of Hawai'i ("the State"), by and through Anne E. Lopez, Attorney General, filed its memorandum in opposition on April 19, 2024, and Defendants filed their reply on April 26, 2024. [Dkt. nos. 81, 82.] This matter came on for hearing on July 12, 2024. The Defendants' Motion is hereby granted in part and denied in part for the reasons set forth below. The State's First Amended Complaint, originally filed on November 6, 2023 in state court, is dismissed, but the State is granted leave to file a second amended complaint.

BACKGROUND

The State filed its original Complaint in the State of Hawai'i Circuit Court of the First Circuit ("the state court") on October 4, 2023. See Notice of Removal of Civil Action Under 28 U.S.C. §§ 1442(a)(1) and 1446, filed 11/17/23 (dkt. no. 1) ("Notice of Removal"), Declaration of C. Michael Heihre ("Heihre Removal Decl."), Exh. E (copies of filings in the state court) at PageID.730-74 (Complaint). The State filed its First Amended Complaint on November 6, 2023 ("Amended Complaint"). See Heihre Removal Decl., Exh. A (Amended Complaint).[1]

Express Scripts removed the action based on the federal-officer-removal statute, Title 28 United States Code Section 1442(a)(1). See Notice of Removal at ¶¶ 16-18. Caremark filed a Supplemental Notice of Removal on November 17, 2023. [Dkt. no. 8.] Caremark also invoked federal-officer removal. [Id. at ¶ 4.] The State filed a Motion to Remand on November 29, 2023, and the Motion to Remand was denied in an order issued on May 1, 2024 ("5/1 Order"). [Dkt. nos. 29, 85.[2]]

I. Allegations of the Amended Complaint

The State alleges that, "[f]rom 2014 to 2020, prescription drug prices increased by 33%, outpacing inflation and price increases for any other medical commodity or service," and making "life-saving medications unaffordable for many Americans – particularly seniors." [Amended Complaint at ¶¶ 34-35.] "In 2020, it was estimated that high out-of-pocket costs for drugs would cause 1.1 million premature deaths of seniors in the Medicare program over the next decade, and lead to an additional $177.4 billion in avoidable Medicare medical costs." [Id. at ¶ 37.]

***2** The State cites insulin as an example and alleges:

> In 1999, Humalog (insulin) was affordably priced at $21. Twenty years later, the price had increased by more than 1000% to $332. Due to unprecedented pressure on [pharmacy benefit managers ("PBMs")] and insulin manufacturers, insulin costs are finally starting to decrease. For example, on April 3, 2019, Express Scripts announced the launch of its Patient Assurance Program, which Express Scripts claims will "ensure eligible people with diabetes in participating plans pay no more than $25 for a 30-day supply of insulin." Unfortunately, PBMs have not provided this same type of broad relief for the high cost of drugs other than insulin. Further, PBMs have not provided restitution for the prior years' worth of overpayments and their promise to offer insulin at reduced prices is not indefinite.

[Id. at ¶ 38 (footnotes omitted).]

The State alleges that, although PBMs are administrators hired by third-party payers for the benefit of consumers,

PBMs have developed a business model that maximizes PBM profits through inflated prices for brand-name prescription drugs. [Id. at ¶¶ 5-7.] PBMs "create[e] drug formularies — a list of prescription drugs covered by health plans tiered according to consumers' cost-share obligations (*e.g.*, tier 1 drugs require a $5 co-payment, tier 2 drugs require a $10 co-payment)." [Id. at ¶ 5.] Drug manufacturers pay rebates and fees to PBMs to obtain preferred placement on the drug formularies. The price that consumers or insurers are charged includes the rebates and fees, but consumers are not aware of this. [Id. at ¶¶ 8-10.] PBMs typically retain a portion of the rebates. [Id. at ¶ 13.] PBMs will "exclude one or more drugs used to treat the same condition from a PBM formulary to intensify competition among manufacturers." [Id. at ¶ 15.] Drug manufacturers typically increase a drug's wholesale acquisition cost ("WAC"), also known as the "list price" or "sticker price," so that the rebate does not decrease the manufacturer's target revenue. [Id. at ¶ 16.] The State alleges that,

> since 2014, there has been a fundamental shift in payments from prescription drug manufacturers to PBMs. Manufacturer payments to PBMs and other intermediaries have risen by over 16% per annum and now constitute 40% or more of brand-name prescription drug costs. In 2013, the manufacturer Sanofi offered rebates for insulin products between 2% and 4% for preferred placement on CVS Caremark's formulary. By contrast, in 2018, Sanofi's rebates for insulin products were as high as 56% for preferred formulary placement.

[Id. at ¶ 17 (footnotes omitted).]

The State contends PBMs' practice of using rebates and fees to manipulate the price of prescription drugs harms consumers by: 1) increasing consumers' out-of-pocket payments, which are tied to a drug's WAC; 2) increasing the likelihood that consumers will change medications "for reasons other than a drug's efficacy, side effects, or clinical outcome," which can be particularly harmful because some drugs are more effective for some patients than other drugs made to treat the same condition; and 3) artificially inflated drug prices affect persons other than patients who are served by a PBM, *e.g.*, uninsured patients must pay the high list prices that results from the PBM's practices. [Id. at ¶ 20.]

***3** "Defendants collectively manage 80% of prescription drug benefits for more than 220 million Americans. As such, placement on their formularies is a significant bargaining chip when negotiating drug rebates." [Id. at ¶ 14.] Defendants are all registered to do business in Hawai'i and provide PBM services in Hawai'i. See id. at ¶¶ 23, 26, 29. The State investigated PBM involvement, but Caremark and OptumRx only produced data regarding insulin products. Express Scripts produced data regarding insulin products and one other product. [Id. at ¶ 18.] The State therefore used insulin as a case study in its investigation, [id.,] but the State's lawsuit is not limited to insulin and other diabetes medication, [id. at ¶ 22].

The specific statements that the State bases its claims upon are quoted in paragraphs 67 to 69 of the Amended Complaint. See id. at pgs. 18-20 & n.28-44. In general, these statements fall into the following categories:

a. Misrepresenting that the Defendants function to lower the cost of prescription drugs;

b. Misrepresenting that rebates and other payments from manufacturers lower the cost of prescription drugs;

c. Misrepresenting that rebates and other payments from manufacturers do not inflate the WAC price for brand-name prescription drugs;

d. Misrepresenting that formulary decisions are evidence and/or value based;

e. Failing to disclose that the cost share payments insured consumers pay for brand-name prescription drugs are tied to inflated WAC prices rather than the prices that Defendants and/or third-party payers actually pay for prescription drugs;

f. Failing to disclose that the Defendants financially benefit from inflated WAC prices, which allow them to negotiate substantial rebates and other payments from manufacturers for brand-name prescription drugs;

g. Failing to disclose that the Defendants financially benefit from preferring and/or excluding certain prescription drugs in their formularies; and

h. Failing to disclose that formulary exclusions are not based on the best clinical interests of the patient.

See id. at ¶¶ 137.a-137.h. The State alleges this conduct is ongoing, and Defendants' misrepresentations and omissions are material and likely to mislead consumers and third-party payers. [Id. at ¶¶ 138-39.]

The State brings this action pursuant to Hawai'i Revised Statutes Section 480-2 to prevent unfair or deceptive acts or

practices ("UDAP") and unfair methods of competition in trade or commerce ("UMOC"). [Id. at ¶ 21.] The State brings the following claims: a deceptive acts and practices claim under Section 480-2 ("Count I"); an unfair acts and practices claim under Section 480-2 ("Count II"); a UMOC claim under Section 480-2 ("Count III"); and a claim, pursuant to Section 480-2 and Hawai'i Revised Statutes Section 480-14, for treble damages suffered by the State itself ("Count IV").

II. The Motion

Defendants argue all of the claims in the State's Amended Complaint should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6) because the State fails to plead a claim upon which relief can be granted. [Motion at 3.] Defendants seek dismissal with prejudice. [Motion, Mem. in Supp. at 25.]

Defendants argue the State's claims fail as a matter of law because: Defendants do not interact with the consumers; the State has not alleged, and cannot allege, that Defendants' statements about their rebate-negotiation practices are likely to mislead consumers when they purchase insulin or other prescription drugs; the State has not, and cannot, allege that Defendants engaged in unfair or deceptive acts or practices in Defendants' rebate negotiations;[3] and Defendants' negotiations with drug manufacturers stimulate competition. [Id. at 1-2.] Defendants argue the damages claimed by the State are not caused by Defendants' actions, but by the drug manufacturers' decisions to raise their drug prices. [Id. at 2.] Defendants also argue the State's restitution claim should be dismissed because it is an attempt to avoid the requirements of Hawai'i Revised Statutes Chapter 480. [Id. at 3.]

DISCUSSION

***4** All of the State's claims allege violations of Hawai'i Revised Statutes Section 480-2. See Amended Complaint at pgs. 40-43. Section 480-2 states:

> (a) Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful.
>
> (b) In construing this section, the courts and the office of consumer protection shall give due consideration to the rules, regulations, and decisions of the Federal Trade Commission and the federal courts interpreting section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)), as from time to time amended.
>
> (c) No showing that the proceeding or suit would be in the public interest (as these terms are interpreted under section 5(b) of the Federal Trade Commission Act) is necessary in any action brought under this section.
>
> (d) No person other than a consumer, the attorney general or the director of the office of consumer protection may bring an action based upon unfair or deceptive acts or practices declared unlawful by this section.
>
> (e) Any person may bring an action based on unfair methods of competition declared unlawful by this section.

The Hawai'i Supreme Court has stated that:

> **Unfair** act UDAP claims are distinct from deceptive act UDAP claims. To violate HRS § 480-2, a plaintiff may show that an act or practice is deceptive **or** unfair. See Bronster v. U.S. Steel Corp., 82 Hawai'i 32, 50-51, 919 P.2d 294, 312-13 (1996) (jury instructions wrongly conflated deceptive acts and unfair acts under UDAP)....

State ex rel. Shikada v. Bristol-Myers Squibb Co., 152 Hawai'i 418, 443, 526 P.3d 395, 420 (2023) (emphases in original).[4]

I. Count I – Deceptive Acts and Practices Claim

Count I alleges Defendants violated Section 480-2 by "engag[ing] in deceptive acts or practices in trade or commerce" through the actions and omissions in paragraphs 137.a through 137.h, quoted *supra*. See Amended Complaint at ¶¶ 137-137.h.

The Hawai'i Supreme Court has stated:

> Materiality is an essential element of a UDAP deceptive acts violation. See Courbat [v. Dahana Ranch, Inc.], 111 Hawai'i [254,] 262, 141 P.3d [427,] 435 [(2006)] (To prove a deceptive act or practice under UDAP, a plaintiff must show "(1) a representation, omission, or practice that (2) is likely to mislead consumers acting reasonably under the circumstances where (3) the representation, omission, or practice is material.") ....

Bristol-Myers, 152 Hawai'i at 443, 526 P.3d at 420.

> This test is objective, "turning on whether the act or omission 'is likely to mislead consumers' ... as to information 'important to consumers' ... in making a decision regarding the product or service." Courbat, 111

> Hawai'i at 262, 141 P.3d at 435 (citations omitted). "Hawaii's consumer protection laws look to a reasonable consumer, not the particular consumer," and thus do not require an individualized showing of reliance. Yokoyama v. Midland Nat'l Life Ins. Co., 594 F.3d 1087, 1092 (9th Cir. 2010); see also In re Kekauoha-Alisa, 674 F.3d [1083,] 1091 [(9th Cir. 2012)] ("There need not be an intent to deceive nor actual deceit." (citation omitted)). Ordinarily, the question of whether a practice constitutes an unfair or deceptive trade practice is a question of fact. See Balthazar [v. Verizon Haw., Inc.], 109 Hawai'i [69,] 72 n.4, 123 P.3d [194,] 197 n.4 [(2005)].

***5** Weisse v. LG Elecs., Inc., 650 F. Supp. 3d 1078, 1093–94 (D. Hawai'i 2023). Information that is important to consumers is " 'likely to affect their choice of, or conduct regarding, a product.' " Baskin v. EC Paia LLC, CIVIL NO. 20-00216 WRP, 2020 WL 9762818, at *6 (D. Hawai'i Nov. 13, 2020) (quoting Courbat v. Dahana Ranch, Inc., 141 P.3d 427, 435 (Haw. 2006)).

Because a deceptive acts and practices UDAP claim involves misleading consumers, it involves allegations of fraud or mistake, and therefore the heightened pleadings standard of Federal Rule of Civil Procedure 9(b) applies. See Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally."). This district court has stated:

> Rule 9(b) therefore requires the pleading to provide an "account of the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." Swartz v. KPMG LLP, 476 F.3d 756, 764 (9th Cir. 2007) (citation and internal quotation marks omitted). A plaintiff must offer something greater "than the neutral facts necessary to identify the transaction." Vess v. Ciba-Geigy Corp. USA, 317 F.3d 1097, 1106 (9th Cir. 2003). Instead, he or she must identify "what is false or misleading about a statement, and why it is false." Id. (citation omitted). Rule 9(b)'s heightened requirements apply "where a claim is 'grounded in fraud' or 'sound[s] in fraud,' even if fraud is not an essential element of the cause of action." In re Finjan Holdings, Inc., 58 F.4th 1048, 1057 (9th Cir. 2023) (citing Vess, 317 F.3d at 1103).

Hoang v. Hulme, CIVIL NO. 23-00384-JAO-RT, 2024 WL 1406268, at *5 (D. Hawai'i Feb. 1, 2024) (alteration in Hoang). "The claim must be accompanied by the who, what, when, where and how of the misconduct charged, and set forth more than the neutral facts identifying the transaction." Weisse, 650 F. Supp. 3d at 1094 (citing Kearns v. Ford Motor Co., 567 F.3d 1120, 1124 (9th Cir. 2009)).

At the outset, this Court rejects the State's argument that the State can base its deceptive acts and practices claim on allegedly material representations that Defendants made to third-party payers. The State argues those third-party payers are consumers for purposes of Chapter 480 because they are consumers of Defendants' services. The State also emphasizes that the third-party payers have direct contact with members of the public who utilize the prescription drugs at issue in this case. See Mem. in Opp. at 10-11. For purposes of Chapter 480: " 'Consumer' means a natural person who, primarily for personal, family, or household purposes, purchases, attempts to purchase, or is solicited to purchase goods or services or who commits money, property, or services in a personal investment." Haw. Rev. Stat. § 480-1. The third-party payers are not natural persons, and therefore they cannot constitute consumers for purposes of the State's Chapter 480 claims in this case.

The State also argues that, even if the third-party payers are not consumers, Defendants' alleged misrepresentations to third-party payers can support a deceptive acts or practices claim because the misrepresentations are material to consumers' choice of, or conduct regarding, prescription drugs. The State asserts a consumer has the ability to choose a different health plans if the consumer is dissatisfied with the PBM that his current health plan uses. [Mem. in Opp. at 10.] However, this theory of materiality is not supported by the factual allegations of the Amended Complaint and will not be considered in this Court's analysis of whether Count I survives dismissal.

***6** The State also urges this Court to follow the Federal Trade Commission ("FTC") policy that express misrepresentations are presumptively material. [Id.] Section 480-2(b) states that: "In construing this section, the courts ... shall give due consideration to the rules, regulations, and decisions of the Federal Trade Commission and the federal courts interpreting section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)), as from time to time amended." The FTC's relevant policy statement provides:

> The third element of deception is materiality. That is, a representation, omission or practice must be a material one for deception to occur. A 'material' misrepresentation or practice is one which is likely to affect a consumer's choice of or conduct regarding a product. In other words, it is

information that is important to consumers. If inaccurate or omitted information is material, injury is likely.

The Commission considers certain categories of information presumptively material. First, the Commission presumes that express claims are material. As the Supreme Court stated recently, '[i]n the absence of factors that would distort the decision to advertise, we may assume that the willingness of a business to promote its products reflects a belief that consumers are interested in the advertising.' Where the seller knew, or should have known, that an ordinary consumer would need omitted information to evaluate the product or service, or that the claim was false, materiality will be presumed because the manufacturer intended the information or omission to have an effect. Similarly, when evidence exists that a seller intended to make an implied claim, the Commission will infer materiality.

The Commission also considers claims or omissions material if they significantly involve health, safety, or other areas with which the reasonable consumer would be concerned. Depending on the facts, information pertaining to the central characteristics of the product or service will be presumed material. Information has been found material where it concerns the purpose, safety, efficacy, or cost of the product or service. Information is also likely to be material if it concerns durability, performance, warranties or quality. Information pertaining to a finding by another agency regarding the product may also be material.

Where the Commission cannot find materiality based on the above analysis, the Commission may require evidence that the claim or omission is likely to be considered important by consumers. This evidence can be the fact the product or service with the feature represented costs more than an otherwise comparable product without the feature, a reliable survey of consumers, or credible testimony.

In re Cliffdale Assocs., Docket 9156, 1984 WL 565319 (F.T.C. Mar. 23, 1984), App'x (Federal Trade Commission Policy Statement on Deception, dated 10/14/83) at *49-50 (footnotes omitted) (quoting Central Hudson Gas & Electric Co. v. PSC, 447 U.S. 557, 567 (1980)).

The three-part test for deceptive acts or practices claims that the Hawai'i Supreme Court adopted in Courbat is taken from Cliffdale Associates and its analysis of the FTC's Policy Statement on Deception. See Courbat, 111 Hawai'i at 262, 141 P.3d at 435. However, in adopting that three-part test, the Hawai'i Supreme Court in Courbat did not adopt the presumption of materiality that the State relies upon here. Further, there has not been a subsequent case adopting the presumption of materiality described in the FTC policy statement. In the absence of case law from the Hawai'i Supreme Court addressing whether the FTC's presumption of materiality applies to Section 480-2 claims, this Court "must predict how the [Hawai'i Supreme Court] would decide the issue using intermediate appellate court decisions, decisions from other jurisdictions, statutes, treatises, and restatements as guidance." See Trishan Air, Inc. v. Fed. Ins. Co., 635 F.3d 422, 427 (9th Cir. 2011) (quotation marks and citation omitted). Based on Courbat and the lack of subsequent case law adopting or applying the presumption, this Court predicts that the Hawai'i Supreme Court would hold that the FTC's policy that express misrepresentations are presumptively material does not apply to Section 480-2 claims.

***7** This Court concludes that Count I of the Amended Complaint fails to plead a claim that satisfies the Rule 9(b) heightened pleading standard because the State has failed to plead adequate factual allegations regarding materiality. Since Count I must be dismissed on that basis alone, it is not necessary to address Defendants' other arguments regarding Count I, such as the puffery argument.[5] Defendants' Motion is granted insofar as Count I is dismissed. However, the dismissal is without prejudice because it is possible for the State to cure the defects in Count I by amendment. See Hoang v. Bank of Am., N.A., 910 F.3d 1096, 1102 (9th Cir. 2018) ("Dismissal with prejudice and without leave to amend is not appropriate unless it is clear ... that the complaint could not be saved by amendment." (quotation marks and citation omitted))).

II. Count II – Unfair Acts and Practices Claim

Count II alleges "Defendants engaged in unfair acts or practices in trade or commerce in violation of HRS § 480-2 by engaging in a scheme to inflate the WAC price for prescription drugs to allow the Defendants to extract higher fees." [Amended Complaint at ¶ 143.]

"A practice is unfair if it (1) offended public policy, (2) was immoral, unethical, oppressive, or unscrupulous, or (3) substantially injured Hawai'i consumers." Bristol-Myers, 152 Hawai'i at 443, 526 P.3d at 420 (citing Hungate v. Law Office of David B. Rosen, 139 Hawai'i 394, 411, 391 P.3d 1, 18 (2017)).[6] Materiality is not required in an unfair acts or practices claim. Id. at 444, 526 P.3d at 421. The Hawai'i Supreme Court has stated:

> Our UDAP caselaw does not require a plaintiff to prove all three prongs of unfair acts. Rather, "[a] practice may be unfair because of the degree to which it meets one of the criteria or because to a lesser extent it meets all three." Hungate, 139 Hawai'i at 411, 391 P.3d at 18 (quoting Kapunakea Partners v. Equilon Enters., LLC, 679 F. Supp. 2d 1203, 1210 (D. Haw. 2009)).
>
> This conflicts with the federal approach. Congress amended the FTC Act in 1994. Now, plaintiffs suing under the FTC Act must prove substantial injury (and more) for an unfair acts claim. See LabMD, Inc. v. Fed. Trade Comm'n, 894 F.3d 1221, 1226 n.10 (11th Cir. 2018) (explaining that "for an act or practice to be unfair, the act or practice [1] causes or is likely to cause substantial injury to consumers [2] which is not reasonably avoidable by consumers themselves and [3] not outweighed by countervailing benefits to consumers or to competition.") (quoting 15 U.S.C. § 45(n)) (cleaned up)).

Id. at 445, 526 P.3d at 422 (alteration in Bristol-Myers) (footnote omitted). The State alleges that Defendants' conduct satisfies all three prongs. See Amended Complaint at ¶ 144.

A. Pleading Standard

[C]laims made under the "unfair" prong of UDAP do not ordinarily require compliance with the heightened pleading standard. But that is only true when the claims are not grounded in fraudulent conduct. See Ryan v. Salisbury, 380 F. Supp. 3d 1031, 1049 (D. Haw. 2019); Soule [v. Hilton Worldwide, Inc.], 1 F. Supp. 3d [1084,] 1090 [(D. Hawai'i 2014)]. Both the Ninth Circuit and this Court have held that state-law UDAP claims must be pleaded with particularity when the claims are based on fraudulent conduct. See Kearns v. Ford Motor Co., 567 F.3d 1120, 1122 (9th Cir. 2009) (affirming district court's Rule 9(b) dismissal of California UDAP claim even though the district court had not separately analyzed the allegations under the unfair prong); Smallwood v. NCsoft Corp., 730 F. Supp. 2d 1213, 1232-33 (D. Haw. 2010) (holding that claims under Hawai'i's UDAP laws were based on "fraudulent concealment" and thus required pleading with particularity); see also Long v. Deutsche Bank Nat'l Tr. Co., No. 10-cv-00359 JMS/KSC, 2011 WL 2650219, at *7 (D. Haw. July 5, 2011) ("[W]here a chapter 480 claim is based on fraudulent acts, a plaintiff must plead with particularity.").

***8** Aquilina v. Certain Underwriters at Lloyd's Syndicate #2003, 407 F. Supp. 3d 1051, 1066 (D. Hawai'i 2019) (some alterations in Aquilina) (some citations omitted). This Court agrees with the district court's analysis in Aquilina and concludes that Count II of the Amended Complain must satisfy the Rule 9(b) pleading standards because the State's unfair acts and practices claim is based on an allegedly fraudulent scheme to inflate prescription drug prices.

B. *Hungate* Three-Prong Analysis

1. Offends Public Policy

"Public policy covers a broad range, from state and federal law, to common law, to Hawai'i policy." Bristol-Myers, 152 Hawai'i at 447, 526 P.3d at 424 (citation omitted). In Bristol-Myers, the Hawai'i Supreme Court held that the trial court made sufficient findings to support its conclusion that the defendants' conduct offended public policy. Id. at 448, 526 P.3d at 425. The supreme court stated:

> Pharmaceutical companies have a common law duty to warn consumers "when the risks of a particular drug become apparent." [Merck Sharp & Dohme Corp. v.] Albrecht, 139 S. Ct. [1668,] 1677 [(2019)].
>
> The court-as-factfinder concluded that the companies aimed to avoid their common law duty by: "suppressing research and continuously and repeatedly failing to further investigate the risks of reduced platelet inhibition in poor metabolizers." In its findings, the court determined that the companies knew - from the moment Plavix launched - about the diminished effects of Plavix in non-White populations. It maintained that the companies did not volunteer this information to the [Food and Drug Administration ("FDA")]. The court further found the companies avoided funding studies which could draw more attention to the variability of response, for instance, by rejecting a study on aspirin resistance because "it could lead to a similar trial on [Plavix] resistance."
>
> The companies' actions, the court found, set back the research into CYP2C19 by consciously, repeatedly, and actively avoiding the poor responder problem. All this, according to the court, was to avoid "negative marketing implications" for Plavix.
>
> Preventing risks from becoming apparent for financial gain offends Hawai'i public policy. Hawai'i law cannot incentivize drug companies to ignore safety risks in the hope that everything will turn out all right in the end. Even if the drug proves to be safe, avoiding investigation

> into known safety issues in order to keep profits up offends public policy. See, e.g., 21 CFR §§ 314.80, 314.81 (requiring a continuing duty of surveillance and post-marketing reporting to the FDA of adverse drug experiences).

Id. at 447, 526 P.3d at 424 (some alterations in Bristol-Myers).

In contrast, the instant case does not involve misrepresentations by any of Defendants to consumers, nor does it involve the failure to make representations that Defendants had a duty to make to consumers. Cf. id. at 422, 526 P.3d at 399 ("This case is about whether two pharmaceutical companies — Defendants-Appellants Bristol-Myers Squibb and Sanofi — violated Hawai'i's Unfair or Deceptive Acts or Practices law (UDAP) by misleading the public about the safety and efficacy of their antiplatelet drug, Plavix."). Thus, the State's unfair acts and practices claim in the instant case cannot be based upon the public policies described in Bristol-Myers.

***9** The Amended Complaint makes only a conclusory allegation that Defendants' acts and practices offend public policy; the Amended Complaint does not identify a specific public policy. See Amended Complaint at ¶ 144. Further, the State's memorandum in opposition does not identify a public policy that Defendants' allegedly unfair acts or practices offend.

2. Immoral, Unethical, Oppressive, or Unscrupulous

The Hawai'i Supreme Court has noted that the "immoral, unethical, oppressive, or unscrupulous" prong presents another difference between Hawai'i law and federal law:

> The FTC scrapped Sperry's second criteria long ago. In its 1980 Unfairness Policy Statement, the FTC called the "immoral, unethical, oppressive, unscrupulous" features of an unfair act or practice "largely duplicative." "Conduct that is truly unethical or unscrupulous," the FTC continued, "will almost always injure consumers or violate public policy as well." FTC Policy Statement on Unfairness.
>
> https://www.ftc.gov/legal-library/browse/ftc-policy-statement-unfairness
>
> [https://perma.cc/3VA6-JMFK].

Bristol-Myers, 152 Hawai'i at 448 n.33, 526 P.3d at 425 n.33 (referring to the three criteria for an unfair practice in F.T.C. v. Sperry & Hutchinson Co., 405 U.S. 233, 244 n.5 (1972)). In Bristol-Myers, the Hawai'i Supreme Court held that the trial court made sufficient findings to support its conclusion that the defendants' conduct was immoral. Id. at 448, 526 P.3d at 425. The supreme court stated:

> The court's findings also animate its determination that the companies behaved in an "immoral, unethical, oppressive, unscrupulous" manner. The court determined that the companies prioritized profits over patients: defendant companies "buried their heads in the sand" about the problems with Plavix to protect the corporate bottom line. The court found the companies "continued to deny" the issues surrounding poor response to the drug despite evidence to the contrary, giving the impression that no one had any reason to be alarmed. See Hawaii Cmty. Fed. Credit Union v. Keka, 94 Hawai'i 213, 229, 11 P.3d 1, 17 (2000) (describing conduct as unethical and unscrupulous when defendant attempted to convince a family to execute loan documents through false assurances about a lower interest rate).

Id. at 447–48, 526 P.3d at 424–25 (footnote omitted).

The Amended Complaint alleges Defendants' acts and practices committed in furtherance of their "scheme to inflate the WAC price for prescription drugs to allow the Defendants to extract higher fees .... are immoral, unethical, oppressive, and unscrupulous ...." [Amended Complaint at ¶¶ 143-44.] The rebate and formulary-placement strategies described in the Amended Complaint do not rise to the level of the type of conduct such as the conduct at issue in Bristol-Myers (failure to disclose a prescription drug's risks) and Keka (using false assurances about the interest rate). See also Aquilina v. Certain Underwriters at Lloyd's Syndicate #2003, 465 F. Supp. 3d 1088, 1100 (D. Hawai'i 2020) ("Plaintiffs have alleged plausible facts indicating that Underwriters' and Monarch's conduct in these narrow circumstances — selling and placing insurance that did not comply with the obvious needs and express requests (to the Retail Brokers) of the uniquely-situated homeowners — 'offends public policy' and is 'unscrupulous or substantially injurious to consumers.' ").

3. Substantially Injures Hawai'i Consumers

***10** "Substantial injury, more so than the other unfair prongs, focuses on consequences for consumers." Bristol-Myers, 152 Hawai'i at 444, 526 P.3d at 421. In a case involving a claim under Title 15 United States Code Section 45(n),[7] the Ninth Circuit stated: "An act or practice can cause 'substantial injury' by doing a 'small harm to a large number of people, or if it raises a significant risk of concrete harm.' " F.T.C. v. Neovi, Inc., 604 F.3d 1150, 1157–58 (9th Cir. 2010),

as amended (June 15, 2010) (quoting Am. Fin. Servs. Ass'n v. FTC, 767 F.2d 957, 972 (D.C. Cir. 1985) (quotation marks and citations omitted) *cert. denied*, 475 U.S. 1011, 106 S. Ct. 1185, 89 L. Ed. 2d 301 (1986)).

The State alleges Defendants' acts and practices harm Hawai'i consumers by increasing the out-of-pocket costs for prescription drugs and by increasing the risk that consumers may have to change their drug therapies for reasons unrelated to the drug's overall effectiveness for them. See Amended Complaint at ¶¶ 113-22, 126-34. These are speculative injuries that do not, particularly not by themselves,[8] support an unfair acts or practices claim.

4. Ruling

The State fails to plead a plausible unfair acts and practices claim against Defendants because the State fails to adequately allege any of the three Hungate prongs, individually or when considered collectively. Count II must therefore be dismissed. See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." (citation and internal quotation marks omitted)). Count II is therefore dismissed, but the dismissal is without prejudice because it is arguably possible for the State to cure the defects in Count II by amendment.

III. Count III – UMOC Claim

The State's UMOC claim is based upon Defendants' alleged "practices that inflate the WAC price for brand-name prescription drugs to allow the Defendants to extract higher fees." [Amended Complaint at ¶ 148.]

***11** "In order to state a claim for unfair methods of competition, a plaintiff must state sufficient facts to set forth the nature of the competition, how the defendant's conduct negatively affected competition, and how the plaintiff was harmed as a result of the defendant's actions." Weisse, 650 F. Supp. 3d at 1095 (citing Davis v. Four Seasons Hotel Ltd., 122 Hawai'i 423, 438, 228 P.3d 303, 318 (2010); HRS § 480-2(a),(e)). In Weisse, the district court ruled

> Plaintiffs have sufficiently alleged the nature of the market — other air conditioner options, presumably available to Hawai'i consumers. ECF No. 43 ¶ 93. But as to harm to competition, Plaintiffs only allege: "Defendants' unfair and deceptive business practices negatively affected competition **by hiding the true market value of the LG PTACs; thus, giving Defendants an unfair market advantage relative to other air conditioner options**." Id. (emphasis added). This allegation is too conclusory to plausibly allege a negative impact on competition; nor can the Court conclude that the allegation of market advantage is plausible when the FAC is devoid of any facts about the market for similar PTACs (*e.g.*, their price, value, warranties, potential for defect, availability within Hawai'i, etc.). "Ordinarily, the factual support needed to show injury to competition must include proof of the relevant geographic markets and demonstration of the restraint's anticompetitive effects within those markets." Sunday's Child, LLC v. Irongate Azrep BW LLC, Civil No. 13-00502 DKW-RLP, 2017 WL 10651861, at *4 (D. Haw. Oct. 27, 2017) (internal quotation marks, alteration, and citation omitted).

Id. (emphasis in Weisse).

In the instant case, Count III alleges:

> Defendants' practices harm competition because they inflate the price for prescription drugs beyond their fair market value and restrict consumers' access to life-saving drugs. In addition, Defendants' practices disadvantage manufacturers unwilling to pay exorbitant rebates and other payments — even if those manufacturers make a superior or more cost-effective prescription drug. Defendants' practices also disadvantage PBMs that are not engaging in similar practices by making them less competitive in the PBM market and lessening their abilities to lower drug costs for their clients and, ultimately, consumers.

[Amended Complaint at ¶ 149.] Based on the standards described in Weisse, this Court concludes that Count III fails to adequately allege the nature of the competition. The allegations the State makes in paragraph 149 are conclusory, and the State fails to allege sufficient factual allegations about the relevant markets - other PBMs that compete with Defendants and/or manufacturers that utilize and compete for Defendants' PBM services. Count III must be dismissed because it fails to state a plausible UMOC claim. However, the dismissal of Count III is without prejudice because it may be possible for the State to cure the defects in this claim by amendment.

IV. Count IV – Claim for Damages Sustained by the State

Count IV alleges a claim pursuant to Hawai'i Revised Statutes Section 480-14 to recover the damages that the State itself incurred as a result of Defendants' Section 480-2 violations.

See Amended Complaint at ¶¶ 153-55. Section 480-14(a) states:

> Whenever the State or any of its political subdivisions or governmental agencies is injured, directly or indirectly, in its business or property by reason of anything forbidden or declared unlawful by this chapter, it may sue to recover threefold the actual damages sustained by it, whether directly or indirectly. The attorney general may bring an action on behalf of the State or any of its political subdivisions or governmental agencies to recover the damages provided for by this section, or by any comparable provisions of federal law.

***12** Because Count IV does not allege separate violations, but rather seeks to recover damages that the State incurred as a result of the violations alleged in Counts I, II, and III, the State's failure to allege plausible Section 480-2 claims in Counts I through III necessarily means that the State also fails to state a plausible Section 480-14(a) claim in Count IV. Count IV must be dismissed, but the dismissal is without prejudice. This Court has concluded that it is arguably possible for the State to cure the defects in Counts I through III, and curing the defects in one or more of those claims would also cure the defect in Count IV.

CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss Plaintiff's First Amended Complaint, filed January 5, 2024, is HEREBY GRANTED IN PART AND DENIED IN PART. Defendants' Motion is GRANTED insofar as the State's First Amended Complaint, filed November 6, 2023 in state court and replaced by the version filed in this district court on August 19, 2024, is DISMISSED. The Motion is DENIED insofar as the dismissal is WITHOUT PREJUDICE. The State is GRANTED leave to file a second amended complaint by **December 16, 2024**.

To the extent that the second amended complaint contains the same type of information that this Court ordered to be sealed in the First Amended Complaint, the State is ORDERED to file that information under seal in the second amended complaint. On or before the **December 16, 2024** deadline, the State shall file a redacted version of the second amended complaint, as well as an unredacted version of the second amended complaint under seal. To the extent that the State intends to add allegations in the second amended complaint that contain other information similar to the information that this Court ordered to be sealed in the First Amended Complaint, the State's counsel is DIRECTED to meet and confer with Defendants' counsel to discuss the information, **at least seven days prior to the filing of the second amended complaint**.

If the parties agree upon proposed redactions that comply with this Court's prior orders regarding sealed filings, the parties are DIRECTED to submit a stipulation for this Court's approval to kobayashi_orders@hid.uscourts.gov. The stipulation shall be accompanied by the proposed redacted version of the second amended complaint and an unredacted version of the second amended complaint. The stipulation must be submitted by the **December 16, 2024** deadline.

If the parties cannot agree on a set of redactions that comply with this Court's prior orders regarding sealed filings, the State is DIRECTED to file a redacted version of the second amended complaint with all of Defendants' proposed redactions, as well as an unredacted version of the second amended complaint under provisional seal. Defendants are DIRECTED to file a motion to seal addressing all of the proposed redactions. Defendants' motion to seal must be filed within **fourteen days after the filing of the State's second amended complaint**. If Defendants fail to file a motion to seal by that date, this Court will order that the unredacted version of second amended complaint be publicly filed.

IT IS SO ORDERED.

DATED AT HONOLULU, HAWAII, October 30, 2024.

All Citations

Slip Copy, 2024 WL 4625719

Footnotes

1 The State's pleadings filed in the state court contained various redactions. Pursuant to this Court's August 13, 2024 entering order granting their motion to seal, Express Scripts and OptumRx filed a version of the Amended Complaint with redactions that were approved by this Court. See Minute Order – EO: Court Order Granting Defendants Express Scripts, Inc. & OptumRx, Inc.'s Moton to Seal Portions of Unredacted First Amended Complaint, filed 8/13/24 (dkt. no. 139); Notice of Submission of Redacted First Amended Complaint Pursuant to Minute Order Filed August 13, 2024 [Dkt.

No. 139], filed 8/19/24 (dkt. no. 143), Exh. A (First Amended Complaint). All subsequent references to the Amended Complaint in this Order refer to the version of the Amended Complaint that is included within docket number 143. An unredacted version of the Amended Complaint was filed under seal on August 13, 2024. [Dkt. no. 140.] The information in the Amended Complaint that is filed under seal is not relevant to this Court's analysis of Defendants' Motion.

2 The 5/1 Order is also available at 2024 WL 1907396.

3 Defendants emphasize that the State operates some of the health plans that contract to receive PBM services, and those plans benefit from rebates that reduce the plans' costs for prescription drugs. [Motion, Mem. in Supp. at 1-2.] The State also receives rebates through Medicaid. [Id. at 4 (citing 42 U.S.C. § 1396r-8(a)(1), (a)(7), (b)(2)).]

4 Bristol-Myers abrogated Bronster, 82 Hawai'i 32, 919 P.2d 294, on grounds other than the recognition that a deceptive acts and practices claims is distinct from an unfair acts and practices claim. See Bristol-Myers, 152 Hawai'i at 446, 526 P.3d at 423.

5 This Court makes no ruling as to those arguments, and Defendants may raise those arguments again in a later proceeding, if appropriate.

6 Bristol-Myers abrogated Hungate, 139 Hawai'i 394, 391 P.3d 1, insofar as Hungate "inharmoniously retained the 'and-or' language" and failed to "clarify whether the appropriate test was fully disjunctive." Bristol-Myers, 152 Hawai'i at 446, 526 P.3d at 423.

7 Title 15 United States Code Section 45(n) states:

> The Commission shall have no authority under this section or section 57a of this title to declare unlawful an act or practice on the grounds that such act or practice is unfair unless the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination.

8 This Court agrees with Defendants that, even though Bristol-Myers held the three ways to prove an unfair act or practice are disjunctive, see 152 Hawai'i at 446, 526 P.3d at 423, Bristol-Myers should not be read as allowing a claim to be established based on substantial injury alone because that would effectively result in strict liability and "would impermissibly read out the word 'unfair' from the UDAP." See Reply at 11 n.5 (citing Keliipuleole v. Wilson, 941 P.2d 300, 304 (Haw. 1997) ("Courts are bound to give effect to all parts of a statute, and that no clause, sentence, or word shall be construed as superfluous, void, or insignificant if a construction can be legitimately found ....") (cleaned up)).

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